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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,449	08/22/2003	Menzo Havenga	2578-4489.1US	9509

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EXAMINER	
MARVICH, MARIA	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,449	HAVENGA ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 14-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment filed 1/18/05. Claims 2-13 have been canceled. Claims 1 and 14-21 have been amended. Claims 1 and 14-21 are pending in the application.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein and, therefore, this action is not final.

Information Disclosure Statement

An IDS filed 12/13/04 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Priority

Acknowledgment is made of submission of the foreign priority document filed in the European Patent Office on 7/8/1998, 98202297.2 filed in English.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 and 15-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 28 of copending Application No. 10/381,088. **This is a new rejection.**

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method for delivering heterologous nucleic acids to a dendritic cell. The instant claims recite use of a recombinant vector of a subgroup C origin which has a chimeric coat protein wherein at least a fiber shaft and knob are of an adenovirus of serotype 11, 16, 35, 40-L and 51. The cited claim 28 of copending Application No. 10/381,088 recite transducing dendritic cells in which isolated dendritic cells are contacted with a vector that has tissue tropism provided by a fragment from adenovirus 16 (claim 14) and this virus comprises protein fragments derived from an adenovirus of subgroup C (claim 18). Furthermore, copending application 10/381,088 contemplates recombinant viruses comprised of ad 35, 11, 51 and 40-L (see e.g. claim 26 and 31). The cited claims of the instant

invention recite that the cells are *in vitro,* which is encompassed by the claims of copending Application No. 10/381,088, which recite a step of isolating the dendritic cells from a donor. It would have been obvious to isolate the cells, as this is required to establish cells for *in vitro* transduction.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the copending Application No. 10/381,088 then two different assignees would hold a patent to the claimed invention of copending Application No. 10/381,088,and thus improperly there would be possible harassment by multiple assignees.

Response to Argument

Applicants' state in regards to the previous claim rejections under the judicially created doctrine of obviousness-type double patenting that the rejection will be addressed upon indication of allowable subject matter. The instant rejection, while new, is based upon the same provisional application 10/381,088. These claims will remain rejected until the instant claims are patented or a terminal disclaimer is filed.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 14-21 are vague and indefinite in that the metes and bounds of "of a " "origin" are unclear. The instant method relies on use of a chimeric vector that is of a subgroup C origin as well as comprising a fiber originating from other serotypes. It is unclear how closely related the recombinant adenoviral vector are to the originating adenovirus and it is also unclear what the functional and structural relationship between the original adenovirus and the resulting recombinant adenovirus are. The metes and bounds of the claimed subject matter are unclear. **This is a new rejection necessitated by applicants' amendment.**

Claims 20 and 21 are vague and indefinite in that the metes and bounds of "in comparison to a wild-type adenovirus" are unclear. The recitation of "wild-type adenovirus" encompasses any one of a multitude of virus, which varies in their antigenicity and replication rates. Therefore, the source of comparison is a relative one with no single set of conditions and the specification does not provide a standard for ascertaining the requisite degree. **This is a new rejection.**

Claims 1 and 14-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection. This is a new matter rejection.**

The limitation that the recombinant adenoviral vector comprises a chimeric coat comprising at least the fiber shaft and knob from adenovirus 11, 16, 35, 40-L or 51 has been added to claim. The specification discloses that the entire fiber protein is substituted in the chimeric proteins. Applicant has not indicated where support for the limitation that the fiber protein comprises the shaft and knob of the second serotype is found. Therefore, the limitation of "a fiber protein wherein at least a fiber shaft and a fiber knob" is impermissible NEW MATTER.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 14-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants recite a genus of recombinant adenoviral vectors that originate in subgroup C and furthermore comprise fibers originating in other serotypes such as serotype 11, 16, 35, 40-L and 51. **This is a new rejection necessitated by applicants' amendment.**

Applicants recite a genus of recombinant adenoviral vectors with a genus of modifications that reduce immune responses to adenoviral vectors in a host compared to wild-

type adenovirus. **This rejection is maintained for reasons of record in the office action mailed 9/15/04 and restated below.**

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

The invention recites a method for delivering a heterologous nucleic acid to dendritic cells using a recombinant adenovirus that is of subgroup C origin or Ad5 origin and comprises the fiber shaft and fiber know of a fiber protein of an adenovirus of another serotype origin such as from adenovirus serotypes 11, 16, 35, 40-L or 51. It is unclear how closely related the resultant vector must be to the adenovirus of origin. By recitation of adenovirus of subgroup C origin, the relationship between structure and function is unclear. The specification discloses generation of chimeric vectors comprising fiber proteins of 11, 16, 35, 51 and 40-L, which exhibited efficient infection of immature dendritic cells (DCs) compared to Ad5 (page 14, paragraph 0053 and page 15, paragraph 0055). Therefore, applicants have demonstrated that recombinant ad5 adenovirus in which the fiber protein is replaced by that of ad 11, 16, 35, 40-L and 51 functions to deliver nucleic acids to dendritic cells. But the specification has failed to convey the relevant identifying characteristics of the recited vectors or provide a description of the chimeric adenovirus such that the structural requirements of the genus of vectors can be envisioned. Given the widely divergent of the recombinant adenovirus that have origins in

subgroup C and in ad 11, 35, 16, 40-L and 51, and the uncertainty of the activity of any of these vectors to deliver heterologous nucleic acids to dendritic cells, it must be considered that any of the recited recombinant adenovirus must be empirically determined. In an unpredictable art, the disclosure of one example would represent to the skilled artisan that applicants were not in possession of claimed genus.

Applicants recite use of recombinant vectors that have been modified such that the immune response against the adenovirus has been reduced compared to wild-type adenovirus. By recitation of modified adenovirus, applicants recite a broad genus of vectors as modifications can encompass a variety of insertions, substitutions, deletions and chimerics. While, applicants teach that the capacity of a host immune response to mount an immune response against adenoviral proteins encode by the adenovirus nucleic acid has been reduced or disabled, there is no disclosure of any modifications such that the immune response to the vectors is reduced. Therefore, applicants have not reduced to practice the claimed invention. Furthermore, the relationship between structure and function is unclear. As well functional data on the immunity of the recombinant vectors of the instant invention is not provided. The specification fails to convey the relevant identifying characteristics of the vectors with reduced immune response such that the structural requirements can be envisioned. Neither applicant nor the prior art provide a correlation between the recombinant adenovirus and their antigenicity. Given the large size and variable nature of modifications and the inability to envision what recombinant vectors will possess a reduced immune response, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of no examples would not represent to the

skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 112, first paragraph, on pages 8-9 of the amendment filed 1/18/05. Applicants argue that the specification discloses " the capacity of a host immune response to mount an immune response against adenoviral proteins encode by the adenovirus nucleic acid has been reduced or disabled".

Applicants' arguments filed 1/18/05 have been fully considered but they are not persuasive. The rejection of claim 21 under 35 USC 112, first paragraph, for lack of written description, is based upon a lack of written description of the genus of vectors that comprise modifications that render an immune response at least partially reduced. Although the instant claims are directed to methods, adequate description of the methods first requires an adequate description of the materials, which provide the means for practicing the invention. The Guidelines for Written Description state "The claimed invention as a whole may not be adequately described if the claims require an essential or critical element which is not adequately described in the specification and which is not conventional in the art". Applicants have not described a genus of vectors with modifications such that an immune response to the vector is at least partially reduced in comparison to wild type.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

August 25, 2004

Daniel M. Sullivan
Patent Examiner
TC 1600